

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20773

MICROBIOLOGY REVIEW(S)

Jordan
JAN 13 1997

REVIEW FOR HFD-160
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #1 OF NDA 20-773
13 January 1997

A. 1. NDA 20-773

APPLICANT: Bracco Diagnostics, Inc.
P.O. Box 5225
Princeton, NJ 08543-5225

2. PRODUCT NAMES: Simethicone Coated Cellulose - SonoRx®

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:

The product is supplied as a single dose suspension for oral administration.

4. METHODS OF STERILIZATION:

The drug product is an oral dosage form and is not required to be sterile. It does however, comply with microbial limits specifications.

5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION:

The product is intended for the delineation of anatomy and the detection and exclusion of pathology in the upper abdomen, including the upper gastrointestinal tract and the retroperitoneum.

B. 1. DATE OF INITIAL SUBMISSION: 30 September 1996

2. DATE OF AMENDMENT: (None)

3. RELATED DOCUMENTS: IND () DMF ()

4. ASSIGNED FOR REVIEW: 9 October 1997

C. REMARKS: The application contains a microbial limit specification of: "no actual or potential pathogens". As written this specification cannot be met. The applicant should be advised to change this specification.

Bracco Diagnostics, NDA 20-773; SonoRx®, Microbiologist's Review #1

D. CONCLUSIONS: The application is not recommended for approval.
Specific comments are provided
and "Microbiologist's Draft of Letter to
Applicant".

/S/

Paul Stinavage, Ph.D.

13 January 1997

PHC 1/13/97

cc: Original NDA 20-773
HFD-160/R. Jordan
HFD-805/Consult File/Stinavage

Drafted by: P. Stinavage, 13 January 1997
R/D initialed by P. Cooney

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JUN 23 1997

REVIEW FOR HFD-160
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #2 OF NDA 20-773
23 June 1997

- A. 1. NDA 20-773
APPLICANT: Bracco Diagnostics, Inc.
P.O. Box 5225
Princeton, NJ 08543-5225
2. PRODUCT NAMES: Simethicone Coated Cellulose - SonoRx®
3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
The product is supplied as a single dose suspension for oral administration.
4. METHODS OF STERILIZATION:
The drug product is an oral dosage form and is not required to be sterile. It does however, comply with microbial limits specifications.
5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION:
The product is intended for the delineation of anatomy and the detection and exclusion of pathology in the upper abdomen, including the upper gastrointestinal tract and the retroperitoneum.
- B. 1. DATE OF INITIAL SUBMISSION: 30 September 1996
2. DATE OF AMENDMENT: 29 April 1997 (Subject of this review)
3. RELATED DOCUMENTS: IND ☒ DMF ☒
4. ASSIGNED FOR REVIEW: 19 May 1997
- C. REMARKS: The amendment provides responses to deficiencies cited in Microbiologist's Review #1 dated 13 January 1997.

Bracco Diagnostics, NDA 20-773; SonoRx®, Microbiologist's Review #2

D. CONCLUSIONS: The application is recommended for approval on the basis of microbial integrity of the drug product.

/S/

23 June 1997

Paul Stinavage, Ph.D.

cc: Original NDA 20-773
HFD-160/R. Jordan
HFD-805/Consult File/Stinavage

Drafted by: P. Stinavage, 23 June 1997

R/D initialed by P. Cooney

/S/

for

PHC

6-23-97